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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,416	12/10/2001	Cynthia C. Bamdad	A-67032-2/RFT/RMS/RMK	1226

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/016,416	BAMDAD ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18 and 20-27* is/are pending in the application.

4a) Of the above claim(s) *26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,20-25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on October 27, 2006 has been entered. The claims pending in this application are claims 18 and 20-27 wherein claim 26 has been withdrawn due to species election. Therefore, claims 18, 20-25, and 27 will be examined.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 18, 20, 24, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.,* (US Patent No.6,319,670 B1, filed on December 23, 1997) in view of Meade *et al.,* (US Patent No. 5,770,369, filed on June 7, 1996) and Roberts *et al.,* (US Patent No. 5,958,791, filed on September 27, 1996).

Sigal *et al.,* teach that method and apparatus for improved luminescence assays using microparticles.

Regarding claims 18, 24, and 27, Sigal *et al.,* teach a composition comprising (i) a sample, (ii) microparticles (ie., colloidal gold particles) comprised of an electrically conductive material having one or more copies of a first assay-ligand immobilized on its surface and a plurality of ECL moieties immobilized on its surface and (iii) a second assay-ligand immobilized on an electrode wherein said first and second assay-ligands are different in structure and/or

specificity (see column 4, last paragraph and column 12, second paragraph) and the ECL moieties include transition metal complexes (see column 9, first paragraph), and claim 18 does not require that a first binding ligand has an ability to interact with a second binding ligand, Sigal *et al.,* disclose an electrode comprising a first binding ligand (ie., said second assay-ligand) and a plurality of colloids each comprising: i) a second binding ligand (ie., said first assay-ligand); and ii) an electron transfer moiety such as a transition metal complex as recited in a) and b) of claim 18 and claim 24. Since Sigal *et al.,* teach that a first assay-ligand and a second assay-ligand are nucleic acids (see column 3, fourth paragraph), Sigal *et al.,* disclose that said first binding ligand is a first nucleic acid and said second binding ligand is a second nucleic acid as recited in claim 27.

Regarding claim 20, Sigal *et al.,* teach that said plurality of colloids comprise a self-assembled monolayer as recited in claim 20 (see column 8, second paragraph).

Sigal *et al.,* do not disclose a substrate comprising an array of electrodes and a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety as recited in a) and c) of claim 18. However, Sigal *et al.,* teach electrochemical cells having electrodes for ECL measurement by detecting light emitted from the working electrode surface (see column 9, first paragraph and column 17, left column), Sigal *et al.,* disclose a detector capable of detecting said electron transfer moiety (ie., ECL) as recited in c) of claim 18.

Meade *et al.,* teach that a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety (see column 27, left column).

Roberts *et al.,* teach advantages of fabricating small electrodes in interdigitated arrays (see column 7, last paragraph bridging to column 8, second paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition recited in claim 18 comprising a substrate comprising an array of electrodes (ie., a plurality of identical electrodes, each has a second assay-ligand) and a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety in view of the patents of Sigal *et al.,* Meade *et al.,* and Roberts *et al.*. One having ordinary skill in the art would have been motivated to do so because Roberts *et al.,* suggest that advantages of fabricating small electrodes in interdigitated arrays "[M]icroelectrodes fabricated in an interdigitated array have inherent advantages in signal detection over more conventional electrode configurations... Scaling down the size of an individual electrode has the advantage of increasing the rate of mass transport, increasing the signal-to-noise (faradaic/charging current) ratio, and decreasing ohmic signal losses... Advantages of fabricating small electrodes in interdigitated arrays go even further by allowing redox cycling of ions back and forth between anode(s) and cathode(s)... This generates much larger currents for detection and allows for the use of extremely small sample volumes" (see column 8) and the simple replacement of one kind of detector (ie., a detector taught by Sigal *et al.,*) from another kind of detector (ie., a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety taught by Meade *et al.,*) during the process of making a composition recited in claim 18 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because the methods capable of detecting an electron transfer moiety are exchangeable (see Meade *et al.,* column 25, fifth paragraph).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

4. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, in view of Meade *et al.*, and Roberts *et al.*, as applied to claims 18, 20, 24, and 27 above, and further in view of Bamdad *et al.*, (US Patent No. 5,620,850, published on April 15, 1997).

The teachings of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, have been summarized previously, *supra.*

Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, do not disclose that said self-assembling monolayer comprises an alkyl chain as recited in claim 21. However, Sigal *et al.*, teach that a self-assembling monolayer is made by functionalized thiol or silane (see column 8, second paragraph).

Bamdad *et al.*, teach that a self-assembling monolayer is made by alkyl thiol functional groups (see columns 9 and 10).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 21 wherein said self-assembling monolayer comprises an alkyl chain in view of the patents of Sigal

et al., Meade *et al.*, Roberts *et al.*, and Bamdad *et al.*. One having ordinary skill in the art would have been motivated to do so because Sigal *et al.*, suggest that functionalized thiol is used to make a self-assembling monolayer (see column 8, second paragraph) and Bamdad *et al.*, have successfully made a self-assembling monolayer using one kind of functionalized thiol, alkyl thiol functional groups (see columns 9 and 10). One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to make a self-assembling monolayer using one kind of functionalized thiol, alkyl thiol functional groups.

5. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, in view of Meade *et al.*, and Roberts *et al.*, as applied to claims 18, 20, 24, and 27 above, and further in view of Gerpheide *et al.*, (US Patent No. 5,565,658, published on October 15, 1996).

The teachings of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, have been summarized previously, *supra.*

Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, do not disclose that said substrate is a printed circuit board as recited in claim 22.

Gerpheide *et al.*, teach that the substrate of an electrode array is a printed circuit board (see Figure 3b).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 22 wherein said substrate is a printed circuit board in view of the patents of Sigal *et al.*, Meade *et al.*, Roberts *et al.*, and Gerpheide *et al.*. One having ordinary skill in the art would have been motivated to do so because Gerpheide *et al.*, have successfully used a printed circuit board as a

substrate to make an array of electrodes and fabrication of electrodes on a printed circuit board would provide an economical and widely available way to make an array of electrodes (see Gerpheide *et al.,* column 5, lines 39-48). One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to use a printed circuit board as a substrate to make an array of electrodes.

6. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.,* in view of Meade *et al.,* and Roberts *et al.,* as applied to claims 18, 20, 24, and 27 above, and further in view of Kayyem *et al.,* (US Patent No. 6,096,273, filed on November 5, 1996).

The teachings of Sigal *et al.,* Meade *et al.,* and Roberts *et al.,* have been summarized previously, *supra.*

Sigal *et al.,* Meade *et al.,* and Roberts *et al.,* do not disclose that said electrodes are gold as recited in claim 23.

Kayyem *et al.,* teach to covalently attach nucleic acids (ie., binding ligands as recited in claim 18) to an electrode such as a gold electrode (see column 4 and Figure 4). The different materials such as gold, silicon, carbon and metal oxide are used to make electrodes and these electrodes are exchangeable (see column 20, lines 40-65).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 23 wherein said electrodes are gold in view of the patents of Sigal *et al.,* Meade *et al.,* Roberts *et al.,* and Kayyem *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple replacement of one kind of electrode (ie., electrodes taught by Sigal *et al.,*)

from another kind of electrode (ie., gold electrodes taught by Kayyem *et al.,*) during the process of making a composition recited in claim 23 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since Kayyem *et al.,* suggest that electrodes are exchangeable (see column 20, lines 40-65),

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.,* in view of Meade *et al.,* and Roberts *et al.,* as applied to claims 18, 20, 24, and 27 above, and further in view of Kayyem *et al.,* (November 5, 1996).

The teachings of Sigal *et al.,* Meade *et al.,* and Roberts *et al.,* have been summarized previously, *supra.*

Sigal *et al.,* Meade *et al.,* and Roberts *et al.,* do not disclose that said transition metal complex is ferrocene as recited in claim 25.

Kayyem *et al.,* teach that electron transfer moieties are different transition metal complexes such as ferrocene. These different transition metal complexes are exchangeable (see column 29, lines 31-42).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition recited in claim 25 wherein said transition metal complex is ferrocene in view of the patents of Sigal *et al.,* Meade *et al.,* Roberts *et al.,* and Kayyem *et al.*. One having ordinary skill in the art would have been motivated to do so because Kayyem *et al.,* have successfully used ferrocene as an electron transfer moiety and the simple replacement of one kind of transition metal complex (ie., a transition metal complex taught by Sigal *et al.,*) from another kind of transition metal complex (ie., a transition metal complex such as ferrocene taught by Kayyem *et al.,*) as an electrode transfer moiety during the process of making a composition recited in claim 25 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since Kayyem *et al.,* suggest that electron transfer moieties for attaching to a nucleic acid are exchangeable (see column 29, lines 31-42),

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

In pages 5 and 6 of applicant's remarks, applicant argues that "the principal of operation of Sigal is chemiluminescence-based, which is different from electronic detection as claimed for the invention. Sigal is based on optical detection of light and NOT a change in voltage. Therefore, replacing the optical detector in Sigal with the voltage detector of Meade totally changes the principal of operation of Sigal" .

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Although the detector taught by Sigal *et al.,* is not used for detecting a change in voltage, since the detector used by Sigal *et al.,* is used for binding assays wherein binding-ligands are nucleic acids (see column 1, second paragraph and column 3, fourth paragraph) while detector capable of detecting a voltage associated with electron transfer from said electron transfer moiety taught by Meade *et al.,* is used for binding assays wherein binding-ligands are nucleic acids (see claims 14-25 in columns 36 and 37) and Meade *et al.,* teach both optical detection method and voltage detection method and suggest that the methods capable of detecting an electron transfer moiety are exchangeable (see Meade *et al.,* column 25, fifth paragraph), replacing the optical detector in Sigal *et al.,* with the voltage detector of Meade *et al.,* does not change the principal of operation of Sigal *et al.*.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

January 5, 2007

FRANK LU
PRIMARY EXAMINER